

**HIV/AIDS Risk Reduction Interventions for
African-American Heterosexual Men**

**Supporting Statement
Part A**

0920-XXXX

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91. A. JUSTIFICATION

92. 1. Circumstances Making the Collection of Information Necessary

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94. The Centers for Disease Control and Prevention requests approval for a new data collection entitled, “HIV/AIDS Risk Reduction Interventions for African-American Heterosexual Men” for two years. The purpose of this information collection is to conduct pilot evaluations of novel HIV risk reduction interventions targeting African American heterosexual men.

95. This project will be conducted by the following sites: a) State University of New York, Downstate-“**SUNY**”(Brooklyn, NY); b) New York Blood Center-“**NYBC**” (Bronx & Harlem, NY); c) University of North Carolina-Greensboro-“**UNCG**” (Greensboro, NC). Each site will evaluate one intervention for feasibility, acceptability and provide preliminary evaluation data of efficacy in reducing HIV risk behaviors.

96.

97. Background

98. The study design for each site (a-SUNY; b-NYBC; c-UNCG) involves a pilot evaluation of three separate interventions using pre-test and three month post-test assessments. Each grantee (SUNY, NYBC, UNCG) will evaluate an intervention using a sample of African American heterosexual men recruited from: a) barbershops in Brooklyn, NY (SUNY); b) street intercepts in Bronx and Harlem, NY (NYBC); and c) colleges in Greensboro, NC (UNCG). The aim of the interventions is to reduce HIV sexual risk behaviors among African American heterosexual men. Primary outcomes of the study include: feasibility and acceptability of the interventions, and preliminary evidence of intervention efficacy in reducing sexual risk behaviors.

99.

100. Following the completion of screening, consent forms, locator information, and baseline assessment, each participant will participate in a HIV risk reduction intervention. The intervention for each site consists of the following: a) SUNY- a brief, single session HIV risk reduction session; b) NYBC- a 4-session, HIV risk reduction group intervention; and c) UNCG - a 5-session HIV risk reduction group intervention.

101.

102. Three months after completing the intervention, participants at each site will return for the Follow-up Assessment). The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with the exception that the Follow-up Assessment will include additional questions regarding acceptability and feasibility of the intervention. The procedures followed for the Baseline Assessment are the same as those for the Follow-up Assessment.

103.

104. This project aims to address the following Goals and Objectives proposed in CDC’s “HIV Prevention Strategic Plan through 2010”: to “Prevent human immunodeficiency virus infection and its related illness and death” and to “Promote responsible sexual behaviors, strengthen community capacity, and increase access to quality services to prevent sexually transmitted diseases and their complications.”

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106.

107. This activity is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

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109.

110. Overview of the data collection system

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112. The study design for each site (a-SUNY; b-NYBC; c-UNCG) involves a pilot evaluation of three separate interventions using pre-test and three month post-test assessments. The data collection system for each site involves screening (Attachments 3a-3c), collecting locator information (Attachments 3d-3f) and conducting a Baseline Assessment and 3-month Follow-up Assessment (Attachments 3g-3i). The screening, baseline and three month follow-up data will be stored on a computer in the research offices at SUNY and NYBC with only an ID number and not with a personal identifier. The linkage file matching name and ID number will be maintained under lock and key in a separate file cabinet from the screening, baseline and follow-up data. For UNCG's online data collections, data from the Screener Form, Locator Form and Baseline and Follow-up Assessments are encrypted during communication between the participant taking the survey and the server hosting the survey web site. An SSL certificate (Secure Socket Layers) is used for the server authentication, data encryption, and message integrity checks. For additional on-line security, the participant's matching unique ID will be maintained on separate server that is not connected to the internet. After the screenings and completion of the Locator Form and the Baseline and Follow-up Assessments, files will be deleted from the server and from the backup tapes. Data from the Screener, Locator Form and Baseline and Follow-up Assessment will be stored in a password-protected directory and will not be linked to any personal identifiable information.

113. For the present study, each grantee (SUNY, NYBC, UNCG) will evaluate an intervention unique to their location: a) SUNY- brief, single session HIV risk reduction session; b) NYBC- a 4-session, HIV risk reduction group intervention; and c) UNCG - a 5-session HIV risk reduction group intervention. The aim of the interventions is to reduce HIV sexual risk behaviors among African American heterosexual men. Primary outcomes of the study include: feasibility and acceptability of the interventions, and preliminary evidence of intervention efficacy in reducing sexual risk behaviors. The participants will be recruited from: a) barbershops in Brooklyn, NY (SUNY); b) street intercepts in Bronx and Harlem, NY (NYBC); and c) colleges in Greensboro, NC (UNCG).

114.

115. Potential participants will be screened for eligibility using Screener Forms (Attachments 3a-3c). Data collectors at SUNY and NYBC will initially record screening information on the Screening Forms. Screening information will later be input into a secure, password-protected computer at which point the paper copies of the Screener Forms will be destroyed. Participants at the UNCG site will complete the screening process on-line using a computer. The data collected will be recorded directly into a secure computerized database.

116.

117. Eligible participants from each site will provide information in identifiable form (IIF) (i.e. names, addresses, telephone numbers), using a Locator Form (Attachments 3d-3f) and complete the Consent Form (Attachments 3g-3i). A linkage file matching name and ID number will be maintained in a locked file cabinet at SUNY, NYBC, or UNCG, separate from the screener, baseline and follow-up data. Only the Principal Investigators,

Project Coordinators and Data Managers at SUNY, NYBC, and UNCG will have access to the file cabinets at their respective sites. Electronic computer files at SUNY, NYBC, and UNCG, containing identifying data (including the linkage file, Locator Form) will be destroyed within 6 months after the end of the intervention trial. Information collected using this form will not be transmitted to the CDC. No individually identifiable information will be transmitted to the CDC for this project.

118. Following consent, participants will complete a Baseline Assessment (Attachments 3g-3i) using ACASI (Audio Computer Assisted Interview) (SUNY and NYBC) or online (UNCG). For UNCG, the Locator Form and Baseline and Follow-up Assessments will be collected on-line using TechTriad (a web hosting and design company with experience in administering secure on-line surveys) and recorded directly into a secure computerized database.

119. Following the baseline assessment (Attachments 3g-3i), each participant will participate in a HIV risk reduction intervention. The intervention for each site consists of the following: a) SUNY- s brief, single session HIV risk reduction session; b) NYBC- a 4-session, HIV risk reduction group intervention; and c) UNCG - a 5-session HIV risk reduction group intervention.

120.

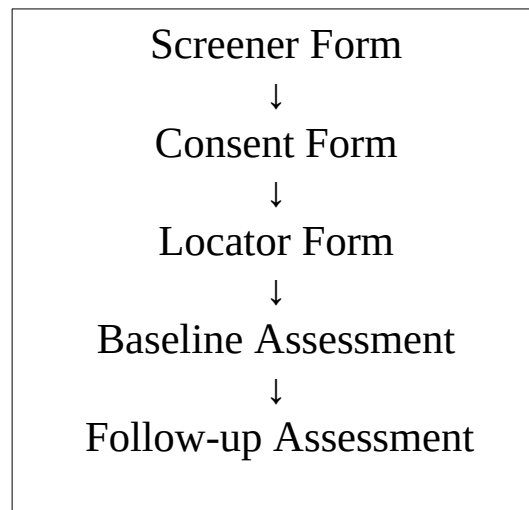
121. Three months after completing the intervention, participants at each site will return for the Follow-up Assessment (Attachments 3g-3i). The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with the exception that the Follow-up Assessment will include additional questions regarding acceptability and feasibility of the intervention. The procedures followed for the Baseline Assessment are the same as those for the Follow-up Assessment.

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123. Data Collection (Flowchart)

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141. **Items of Information to be collected**

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143. The Screener Forms (Attachments 3a-3c) will collect information to ascertain if study participant meet the following eligibility criteria: a) self-identify as male; b) self-identify as African-American/Black; c) understand/read English; d) report unprotected

vaginal or anal intercourse with 2 or more female partners in the last 3 months; e) HIV negative or unknown status; and f) willing and able to provide informed consent.

144.

145. In addition to the overall criteria, additional site-specific inclusion criteria included the following:

146.

a) Age 18-45 years old (SUNY & NYBC)

b) Age 18-24 years old (UNCG)

c) Resident of the South Bronx or Harlem communities (NYBC)

d) Currently enrolled as undergraduates at University of North Carolina Greensboro or North Carolina Agricultural and Technical University (UNCG)

147. Participants are ineligible to participate in the study if they meet any of the following exclusion criteria: a) report injection drug use in last 3 years; b) report oral or anal sex with a man in last 5 years; c) participated in HIV prevention or substance use prevention studies in the previous 6 months.

148.

149. For NYBC, in the event that a potential participant wants to be contacted later to complete screening, brief contact information (i.e., names, address, telephone numbers) will be collected (Attachment 3b). Information collected using this form will not be transmitted to the CDC. No individually identifiable information will be transmitted to the CDC for this project.

150. A Data Collector will then call the potential participant to complete the screening process. Each site will use a Locator Form (Attachments 3d-3f) to collect participant contact information (i.e., name, address, phone number, etc). Information collected using this form will not be transmitted to the CDC. No individually identifiable information will be transmitted to the CDC for this project.

151.

152. The Baseline and Follow-up assessments (Attachments 3g-3i) contain questions about participants' background, health, health care, sexual activity, substance use, and other psychosocial issues. The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with a few additional questions regarding acceptability and feasibility of the intervention

153.

154. More specifically, the data elements collected in both the Baseline and Follow-up Assessments (Attachments 3g-3i) include the following:

- Self-reported demographics
- Sexual behaviors
- Sexual health
- History of incarceration
- Alcohol and drug use
- HIV testing history
- Attitudes, beliefs, self-efficacy
- Perception of sex roles/masculinity
- HIV communication
- Access to healthcare

- Racial discrimination
- Psychological distress
- Intervention Acceptability/Feasibility

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156.

157. The Baseline and Follow-up Assessments (Attachments 3g-3i) will not collect personally identifiable information. No personally identifiable information will be sent to the CDC.

158.

159.

160.

161. Identification of website(s) and website content directed at children under 13 years of age

162.

163. The information collection does not involve use of website(s) or website content directed at children under 13 years of age.

164.

165.

166. 2. Purpose and Use of Information Collection

167.

168. The data to be collected by this pilot study will be used to establish the preliminary efficacy of the three interventions (SUNY-“Barbershop Talk,” NYBC-“Straight Talk,” UNCG-“Brotherhood Retreat”), which have been developed specifically for high-risk heterosexually-active African-American men. The grantees will use a pre-post pilot trial design to assess potential impact on HIV risk related measures from pre- to post-intervention implementation. The primary objective of this study is to test the efficacy of three new multi-session behavioral interventions for determining the feasibility and acceptability of implementing sexual risk reduction interventions for African American heterosexual men. Secondary objectives of this study include assessing the efficacy of the intervention to increase participant’s knowledge, attitude, and intentions toward HIV risk reduction.

169. If the study indicates preliminary efficacy of the intervention(s), a larger study may be designed incorporating “what worked” in multiple settings (in a separate CDC funding announcement or via another source of support).

170. Additionally, those interventions found to be efficacious can be reviewed by the DHAP Prevention Research Synthesis Project and may be featured in the Compendium of Evidence Based Prevention Interventions, which HIV prevention programs use to select appropriate evidence based interventions to implement in the field.

171. The CDC’s Replicating Effective Programs (REP) project identifies and packages HIV behavioral prevention interventions that are tested, science-based, and with demonstrated evidence of effectiveness in reducing risky behaviors (e.g., unprotected sex, having multiple or concurrent partners). These packages are designed, developed, and field-tested by researchers collaborating with community-based partners. The resulting products can guide prevention providers in replicating effective risk-reduction programs in their own settings and communities. Replicating Effective Programs (REP) works with CDC’s Diffusion of Effective Behavioral Interventions (DEBI) project to move effective HIV interventions into program practice. The DEBI project coordinates the dissemination of packaged interventions and provides training and technical assistance. If

effective, the goal then would be to have an intervention product that can be used by prevention providers and state and local health departments throughout the United States.

172.

173. Without the information from this project, CDC will be unable to establish a credible scientific basis for informing the mechanisms available to reduce HIV transmission risk and improving health of African American heterosexual men at increased risk for HIV acquisition and transmission. The results from this project will inform policy makers at CDC and other state and federal agencies, and communities throughout the country about funding, planning, implementing, and evaluating similar efforts.

174.

175. This project is consistent with CDC's mission, in implementing prevention strategies and promoting healthy behaviors. This information collection will increase scientific expertise in the HIV prevention arena and may ultimately provide the information and tools necessary to reduce African American heterosexual men's risk for acquiring and transmitting HIV.

~~176. _____~~

177. This project aims to address the following CDC priorities:

1. "Among people living with HIV, increase the proportion of those who consistently engage in behaviors that reduce risk for HIV transmission or acquisition" and "Reduce the disparities in access to prevention and care services that are experienced by communities of color, women, and special-needs populations" by developing and evaluating sexual risk reduction interventions for African American heterosexual men (who constitute a growing proportion of the epidemic and for whom there is limited effective risk reduction interventions).

178.

2. "To increase the number of evidence-based interventions and the proportion of prevention providers funded by CDC who successfully provide demonstrably effective HIV prevention interventions (including behavioral and biomedical interventions)" by piloting three HIV risk reduction interventions for African American heterosexual men. Evaluation of these unique interventions will be an important step toward expanding CDC's repertoire of evidence-based interventions and would expand the scope of health care providers as prevention providers.

179.

180. This study has several limitations. All data collections will be conducted in the states of New York and North Carolina, and, therefore, may not be generalizable to other locations in the United States, particularly other areas heavily impacted by the HIV/AIDS epidemic. Nevertheless, the findings from this project could be applicable to other areas because HIV transmission patterns among African American heterosexual men in areas with similar demographics of people may be similar. Further, generalization to the larger U.S. population may not be possible because, as with any longitudinal cohort study, there is potential for attrition over the course of the study.

181.

182. Privacy Impact Assessment Information

183. Potential participants will complete Screener Forms (Attachments 3a-3c) to determine eligibility. Eligible participants will complete Locator Forms (Attachments 3d-3f) so that they can be contacted for follow-up activities (i.e. reminders for intervention sessions, completion of follow-up assessments, etc.). The information collected via the Locator Form is in identifiable form (IIF) (i.e. names, addresses, telephone numbers).

However, no individually identifiable information (IIF) will be transmitted from the sites to the CDC.

184.

185. Following consent, participants will complete a Baseline Assessment (Attachments 3g-3i) using ACASI (Audio Computer Assisted Interview) (SUNY and NYBC) or online (UNCG). For UNCG, the Locator Form and Baseline and Follow-up Assessments will be collected on-line using TechTriad (a web hosting and design company with experience in administering secure on-line surveys) and recorded directly into a secure computerized database. Following the baseline assessment (Attachments 3g-3i), each participant will participate in a HIV risk reduction intervention. Three months after completing the intervention, participants at each site will return for the Follow-up Assessment (Attachments 3g-3i). The Follow-up Assessment will cover virtually the same content as the Baseline Assessment with the exception that the Follow-up Assessment will include additional questions regarding acceptability and feasibility of the intervention. The primary purpose of the Baseline/Follow-up Assessments will be to assess preliminary evidence of intervention efficacy.

186.

187. Data collectors at SUNY and NYBC will initially record screening information on the Screening Forms. Screening information will later be input into a secure, password-protected computer at which point the paper copies of the Screener Forms will be destroyed. Participants at the UNCG site will complete the screening process on-line using a computer. The data collected will be recorded directly into a secure computerized database.

188.

189. Eligible participants from each site will provide information in identifiable form (IIF) (i.e. names, addresses, telephone numbers), using a Locator Form (Attachments 3d-3f) and complete the baseline and follow-up assessments (Attachments 3g-3i). A linkage file matching name and ID number will be maintained in a locked file cabinet at SUNY, NYBC, or UNCG, separate from the screener, baseline and follow-up data. Only the Principal Investigators, Project Coordinators and Data Managers at SUNY, NYBC, and UNCG will have access to the file cabinets at their respective sites. Electronic computer files at SUNY, NYBC, and UNCG, containing identifying data (including the linkage file, Locator Form) will be destroyed within 6 months after the end of the intervention trial. Information collected using this form will not be transmitted to the CDC.

190.

191. No individually identifiable information (IIF) will be transmitted from the sites to the CDC for this project.

192.

193.

194.

195. **3. Use of Improved Information Technology and Burden Reduction**

196.

197. This project will use audio-computer assisted self-interviewing (ACASI) technologies for completing the Baseline and Follow-up Assessments (SUNY and NYBC). For these sites, one hundred percent of the responses provided to the Baseline and Follow-up Assessments will be completed using ACASI. Participants at UNCG will complete the Baseline and Follow-up Assessments online using a computer. For UNCG,

the Screener Form (Attachment 3c) and Locator Form (Attachment 3f) will also be completed online. One hundred percent of the responses provided for the Screener Forms, Locator Forms and the Baseline and Follow-up Assessment at UNCG will be completed online.

198.

199.

200. Baseline and Follow-up Assessments will be developed using Questionnaire Development System (QDS) software (NOVA Research Company, Bethesda, Maryland). CDC will provide instructions and technical assistance on how to use the ACASI software, archive the collected data, and transfer the data. Baseline and Follow-up Assessment data will be transferred from study sites to CDC via the secured data network (SDN). No individually identifiable data will be sent to the CDC.

201.

202.

203.——Computer-assisted technology is ideal for in-person data collection because it facilitates the use of highly complex interviewing protocols such as those designed for the current project and. audio files minimize the difficulty that participants with lower literacy levels may have reading the questionnaire items (Des Jarlais et al., 1999; Turner et al. 1998). Another benefit is that the programmed skip patterns will allow for complex question sequencing while substantially reducing the number of questions a participant will have to complete, as the computer program will automatically skip questions that are not relevant based on responses to previous questions. This will increase the instrument's overall efficiency.

204.——

205. 4. Efforts to Identify Duplication and Use of Similar Information

206.

207. Several steps have been taken to prevent duplication of efforts. CDC personnel on this project have reviewed the literature on HIV/AIDS among African American heterosexual men, performed studies of and reported on HIV, attended numerous local, national and international conferences, and communicated frequently with both relevant federal (e.g. HRSA) and non-federal colleagues (e.g. health departments). In addition, multiple search strategies were used to identify published reports of relevant literature and interventions designed to reduce HIV risk among high-risk African American heterosexual men. A comprehensive review of the medical and psychological electronic databases (AIDSLINE, CINHALL, PsychINFO, EMBASE and SocioFile was conducted to review HIV-related research on African American heterosexual men in the United States and the nature of that research. The Computer Retrieval of Information Scientific Projects (CRISP) data base was also searched for federally funded projects involving HIV related research or prevention among high-risk African American heterosexual men. We also reviewed programs in the branch, to identify potential areas of duplication; however, none were found to exist. To our knowledge, the information that will be collected is unique and has not been collected by another federal or non-federal agency.

208.

209.

210. 5. Impact on Small Businesses or Other Small Entities

211.

212. No small businesses will be involved in this data collection. Data collection will not occur in the barbershops nor will data be collected from barbershop personnel.

213.

214.

215. 6. Consequences of Collecting the Information Less Frequently

216.

217. There is no periodic data collection. Participants at each site will complete a Baseline Assessment once and a three month Follow-up Assessment once, (Attachments (3g-3i) in order to assess the feasibility and acceptability of an intervention to reduce sexual risk behaviors among heterosexual African American men.

218. There are no legal obstacles to reduce the burden.

219.

220.

221. 7. Special Circumstances Related to the Guidelines of CFR 1320.5

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223. This request fully complies with the guidelines of 5 CFR 1320.5.

224.

225.

226. 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

227.

228. A 60-Day Federal Register Notice (Attachment 2) was published on April 20, 2010 (vol. 75, pg. 20600). We did not receive public comments.

229.

230. The target population for these interventions is African American heterosexual men. A Community Advisory Board (Attachment 7 for contact information) composed of members of the target population, healthcare providers, as well as members of AIDS and community service organizations has worked with each principal investigator to ensure that intervention and assessment materials are appropriate for the target population. The board members have provided input into all aspects of the study including recruitment methods; how data elements are to be collected, recorded, or reported; clarity of instructions and intervention content; frequency of data collection; and the availability of data. In accordance with congressional mandate (Section 2500 (b), (c), and (d) of the Public Health Service Act, 42, U.S.C. Section 300ee(b),(c)and (d)), all intervention materials and research instruments will be reviewed by the local program review panels to ensure that these materials do not violate community standards.

231.

232.

233. 9. Explanation of Any Payment or Gift to Respondents

234.

235. NYBC

236. Participants will receive the following tokens of appreciation: Baseline assessment (\$25) and 3-month follow-up assessment (\$40). In addition, they will receive a \$4 MetroCard for each visit to assist with transportation.

237.

238. SUNY

239. Participants completing the baseline assessment will receive tokens of appreciation of \$10 cash, plus a gift certificate for a haircut at the barbershop site of recruitment, reimbursable for up to \$20 cash. Participants completing the 3-month follow up assessment will receive a token of appreciation of \$10 cash, plus a gift certificate for a haircut at the barbershop site of recruitment, reimbursable for up to \$20 cash.

Transportation costs will be reimbursed (ascertained via receipts) for transportation to and from the data collection venue for follow-up assessments.

240.

241. UNCG

242. Participants who complete the screening will receive a token of appreciation of a Barnes & Noble gift card worth \$5.00 for use at any Barnes & Noble or UNCG Bookstore. Participants who complete the baseline assessment will receive a \$35 Visa gift card as a token of appreciation. Participants who complete the 3-month follow up assessment will receive a \$35 Visa gift card as a token of appreciation. Investigators at each site drew upon their experience working with this population and community norms to establish the amount and form of these tokens. Further, investigators conferred with local key informants to determine the appropriateness of the tokens for participation in study activities within their own community.

243.

244. This level of gift is the norm for participation in data collection activities in the localities where the project will be conducted. The incentives will complement the intensive efforts by staff to follow-up with participants and maintain updated contact information during the course of the study. Incentives are likely to boost both enrollment and retention rates (Kamb, Rhodes et al. 1998). With increased response rates, the reliability of the data will be improved as the samples will be more representative of the underlying populations of interest.

245.

246. **10. Assurance of Confidentiality Provided to Respondents**

247.

248. CDC is currently seeking a federal Certificate of Confidentiality (PHSA section 301[d]) for the proposed data collections for two sites – NYBC and SUNY. UNCG is not requesting a Certificate of Confidentiality.

249.

250. All data will be treated in as secure a manner as legally possible. The State University of New York, Downstate (SUNY); New York Blood Center (NYBC); and University of North Carolina-Greensboro (UNCG) are responsible for carrying out the following procedures including the collection of data using the Screener Form, Locator Form, Baseline Assessment and Follow-up Assessment.

251.

252. For SUNY and UNCG, no identifiable information will be collected using the Screening Forms (Attachments 3a, 3c). For NYBC, information in identifiable form (IIF), namely contact information (i.e., name, address, phone number) will be collected by a Data Collector using the Screener Form (Attachment 3b) if a potential participant is not able to complete screening when they are first approached and are willing to be contacted by recruitment staff for screening at a later time. For UNCG, the Screener Form (Attachment 3c) will be completed online by potential participants using a computer. Data collected from the Screener Forms will not be transmitted to the CDC.

253.

254.

255. For each site, the Locator Forms (Attachment 3d-3f) will be used to collect personally identifying information (i.e., contact information - name, address, telephone numbers) so that data collectors can follow up with participants to remind them of follow-up visits. Screener Forms (Attachments 3a-3c), and Baseline/Follow-up Assessments (Attachments 3g-3i) will only have a participant ID numbers and will not collect personally identifiable

information. No personal identifiers will be transmitted to the CDC. On a weekly or monthly basis, Baseline and Follow-up data will be encrypted and uploaded to CDC via a secure data network based at CDC.

256.

257.

258. Data collected from the Screener Forms (Attachments 3a-3c) and the Locator Forms (Attachments 3d-3f) for each site will be entered into a computer file which will be stored in an encrypted and password protected computer in the research offices at SUNY, NYBC, UNCG with access only to study team members (i.e., Principal Investigator, Project Coordinator, Data Manager). A linkage file matching name and ID number will be maintained in a locked file cabinet at SUNY, NYBC, or UNCG, separate from the screener, baseline and follow-up data. Only the Principal Investigators, Project Coordinators and Data Managers at SUNY, NYBC, and UNCG will have access to the file cabinets at their respective sites. Electronic computer files at SUNY, NYBC, and UNCG, containing identifying data (including the linkage file) will be destroyed within 6 months after the end of the intervention trial.

259.

260. The local IRBs granted approval for this project on March 4, 2010 – SUNY; March 16, 2010–NYBC; March 22, 2010–UNCG (Attachments 8a-8c).

261.

262.

263. **Privacy Impact Assessment Information**

264.

265. A. This submission has been reviewed by ICRO, who determined that the Privacy Act does not apply. The Privacy Act does not apply because CDC is not collecting personally identifiable information.

266.

267. B. The proposed project is seeking federal Certificates of Confidentiality (PHSA section 301[d]) for the proposed data collections for two sites – NYBC and SUNY.

268.

269. Screener Forms - For NYBC, contact information (i.e., name, address, telephone number) collected during screening (Attachment 3b) will be stored in locked file cabinets in the research office at NYBC until the baseline visit at which time participants can complete the Locator Form (Attachment 3e). For SUNY and NYBC, paper copies of the Screener Forms (Attachments 3a-3b) will be destroyed immediately after the information is entered into an encrypted and password protected computer in the principal investigator's research office with access only to research team members with work-related needs. No personally identifiable data will be sent to the CDC.

270.

271. For each site, information collected via the Locator Forms (name, addresses, telephone numbers) (Attachment 3d-3f) will be entered into an encrypted and password protected computer in the research office with access only to research team members with work-related needs. The paper copies of the Locator Forms (Attachment 3d-3f) will be destroyed immediately after the information is entered into the encrypted and password protected computer. These computer files will be destroyed within 6 months after the end of the intervention trial. Data collected from the Locator Forms (Attachment 3d-3f) will not be sent to the CDC.

272.

273. Contact information for ineligible persons at each site will be destroyed immediately after the trials are complete. The forms for persons who were determined to be ineligible are kept until then to ensure that they will not be approached again for recruitment. For NYBC, contact information collected at screening (Attachment 3b) for those who later decline to participate in the study will be destroyed immediately after the trial is completed. This information is kept until then to ensure that they will not be approached again for recruitment.

274.

275. Consent Forms (Attachments 4a-4c) will also be stored in a separate locked file cabinet in the respective research offices at SUNY, NYBC, or UNCG. Only the Principal Investigators, Project Coordinators and Data Managers will have access to the Consent Forms at their respective sites.

276.

277. The screening, baseline and three month follow-up data will be stored on a computer in the research offices at SUNY and NYBC with only an ID number and not with a personal identifier. The linkage file matching name and ID number will be maintained under lock and key in a separate file cabinet from the screening, baseline and follow-up data.

278.

279. For NYBC, data will be backed up daily on local password-protected servers secured in the New York Blood Center MIS department. For SUNY, the Information Systems Division will perform daily automated backups on a digital linear tape system. All data stored on the servers are password protected and encrypted. Only the Principal Investigators, Project Coordinators and Data Managers will have access to these disks following their transfer at each of their respective sites. Data will be deleted from the data collection computers and from the disks as soon as the data is successfully transferred to the Data Managers' computers. Weekly or monthly (depending on the site), baseline and follow-up data will be encrypted and uploaded to CDC via a secure data network based at CDC. No personally identifiable information will be sent to CDC

280.

281. Access to the research offices at SUNY, NYBC, and UNCG is limited to research personnel only. All research team members/project staff will be trained on and adhere to strict ethical guidelines regarding professional conduct.

282.

283. The following safeguards are applied to the data laptop computers used for SUNY and NYBC: 1) The laptop computers are solely used for the current project activities. 2) All data are encrypted and password protected. 3) Laptop computers are protected by a coded password only known to authorize staff. The laptop computers are kept with the staff at all times when in the field. 5) The computers are secured by the data collectors after the last interview each day. 6) When not in use in the field, the laptop computer is to be locked in a drawer or office.

284.

285. UNCG - The on-line Screening Form (Attachment 3c), Locator Form (Attachment 3f), and Baseline and Follow-up Assessment (Attachment 3h) will be provided through a web hosting and design company with experience in administering secure on-line surveys, called TechTriad (<http://www.techtriad.com>). TechTriad Inc. maintains a strict security policy. Data are not used by TechTriad, sold, or shared with any company, business, or institution other than the main client which is UNCG. The

TechTriad administered Screener, Locator Form and Baseline and Follow-up Assessment will not require separate data entry, thereby reducing the possibility of data entry error. TechTriad will provide the following security measure to insure participant privacy and maintain secured data:

286.

287. An SSL certificate (Secure Socket Layers) is used for the server authentication, data encryption, and message integrity checks. With a valid SSL certificate, internet communications are transmitted in encrypted form and will be delivered privately and unaltered to the server specified (and no other). Therefore, the data from the Screener Form, Locator Form and Baseline and Follow-up Assessments are encrypted during communication between the participant taking the survey and the server hosting the survey web site. TechTriad will store the data from surveys inside a password-protected database on a secured web server until the surveys are completed. The server itself sits behind additional protection that is above-industry-standard security for data, such as various routers and firewalls. For additional on-line security, the participant's matching unique ID will be maintained on separate server that is not connected to the internet. Once TechTriad assigns the participant's email address a unique ID, for further protection, the email addresses will be stored in a separate computer from the unique IDs at TechTriad. TechTriad will maintain the match file on a server that is not connected to the Internet. For additional security, the match file or translation key that connects the unique ID and the email addresses will be stored in a separate computer that has no internet connection (therefore no access to outside sources through WiFi or the internet). After the screenings and completion of the Locator Form and the Baseline and Follow – up Assessments, TechTriad will delete the file from the server and from the backup tapes. Information from the Screener, Locator Form and Baseline and Follow-up Assessment will be stored in a password-protected directory and will not be linked to email addresses. All electronic data will be kept in password-protected electronic files. The Project Coordinator will conduct a weekly back-up and storage of the data through a computer-based CD recorder in the project office. A CD-RW will be used because it will allow data (saved files) to be written, rewritten, and/or erased. Hard copies of datasets (e.g., paper files, CDs) will be maintained separately from lists of names and identification codes for participants and will be kept in a locked file cabinet in the project office. Only the principal investigator and project coordinator will have a key to these files and cabinets. A filing cabinet with a lock is located in the office of the Principal Investigator. All electronic data files will be saved in password protected files in network space available only to approved members of the research team - PI's, Project Coordinator, Graduate Assistant. Signed Consent Forms will be stored in the locked cabinet in the project office in the Department of Public Health Education, UNCG.

288.

- C. Participants from each site will be asked to provide written Informed Consent (Attachments 4a-4c). The Consent Forms provide details of the study procedures, risks, benefits, site contact information, and the nature of privacy and voluntary participation. The consent process also covers information on the trial and that the participant will receive a token of appreciation for their time and travel expenses. Participants are also informed on the Consent Form (Attachments 4a-4c) that they can not enroll in the study more than once and that to keep that from happening, study staff will keep their names. Before a participant signs the Consent Form (Attachments 4a-4c), staff will thoroughly review the form, ask if the participant understands the content of the Consent Form

(Attachments 4a-4c), and answer any questions they may have. Participants will be given a copy of the Consent Form (Attachments 4a-4c) for their records.

289.

290. Participants will be informed that their data will be kept as secure as possible and that the data will be reported in aggregate format and that their name will not be in any report about this study. The privacy section of the Consent Forms (Attachments 4a-4c) also explains to the participant that SUNY, NYBC and UNCG will take all legal steps to protect privacy and that no identifying information will be given to the CDC. Participants will also be informed that no identifying information will be attached to the assessments, just an ID number. Participants are also informed that information will be stored in locked file drawers in the project office at SUNY, NYBC, or UNCG (on a secure computer). Participants are informed that data will be treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

291.

292. D. All participants will be informed of the voluntary nature of their participation during the consent process (Attachments 4a-4c). Almost all the questions in the eligibility Screener Forms (Attachments 3a-3c) and the Baseline and Follow-up Assessments (Attachment 4a-4c) allow the respondent the option of refusing to provide a response. Respondents will be advised that summary (aggregate) and not individual information will be shared in CDC reports and used for the purposes of learning if a intervention developed for African American heterosexual at risk for HIV will help this target population make healthy choices in their lives.

293.

294.

295.

296. **11. Justification for Sensitive Questions**

297.

298. The interventions are based on discussions of sexual behaviors and unprotected sex which involves sensitive questions about sexual and drug use activities. Without this information the study would not be able to answer the primary research question of whether the proposed sexual risk reduction interventions are feasible and acceptable and efficacious in reducing sexual risk behaviors among African American heterosexual men. Participants will be informed that this study involves collecting sensitive information about sexual and drug use behaviors among African American heterosexual men.

299.

300. Participants will be informed at the beginning of each data collection that their participation is voluntary and that they have the right not to answer any questions that they do not wish to answer.

301.

302.

303.

304. **12. Estimates of Annualized Burden Hours and Costs**

305.

306. Table A.12.1 presents participant burden hours across all three study sites (SUNY, NYBC, and UNCG) for completion of the two-year study. For SUNY, the estimated time needed to complete screening 200 potential participants for eligibility is 10 minutes per participant (Attachment 3a). The estimated time for completing the Locator Form (Attachment 3d) for 80 participants is 5 minutes per participant. A total of 80 men will be selected to participate at the SUNY site and will spend 20 minutes completing the Baseline Assessment and

an additional 20 minutes completing the 3 month Follow Up Assessment (Attachment 3g). The total participant burden for this data collection at SUNY is estimated at 94 hours.

307. For NYBC, the estimated time needed to complete screening 214 potential participants for eligibility is 10 minutes per participant (Attachment 3b). A total of 80 men will be selected to participate at the NYBC site and will spend 45 minutes to complete the Baseline Assessment and an additional 45 minutes to complete the Follow up Assessment (Attachment 3h). The estimated time for completing the Locator Form (Attachment 3e) for 80 participants is 5 minutes per participant. The total participant burden for this data collection at NYBC is estimated at 163 hours.

308. For UNCG, the estimated time needed to complete screening 200 potential participants for eligibility is 5 minutes per participant (Attachment 3c). A total of 80 men will be selected to participate at the UNCG site and will spend 20 minutes completing the Baseline Assessment and an additional 20 minutes completing the 3 month follow up assessment (Attachment 3i). The estimated time for completing the Locator Form (Attachment 3f) for 80 participants is 5 minutes per participant. The total participant burden for this data collection at UNCG is estimated at 78 hours.

309.

310. Exhibit A.12.1 Estimated Annualized burden hours

311. Type of Respondent	312. Form Name	313. No. of Respondents	314. No. of Responses per Respondent	315. Average Burden per Response (in hours)	317. Total Annual Burden (in hours)
319. Potential Participants (SUNY)	320. SUNY_Screener (Attachment #3a)	322. 200	323. 1	324. 10/60	325. 33
326. Potential Participants (SUNY)	327. SUNY_Locator Form (Attachment #3d)	328. 80	329. 1	330. 5/60	331. 7
332. Enrolled Participants (SUNY)	333. Baseline Assessment (Attachment #3g)	334. 80	335. 1	336. 20/60	337. 27

338. Enrolled Partici pants (SUN Y)	339. S UNY_F ollow- up Assess ment (Attach ment #3g)	340. 8 0	341. 1	342. 2 0/60	343. 27
344. Potential Partici pants (NYB C)	345. N YBC Screene r (Attach ment #3b)	346. 2 14	347. 1	348. 1 0/60	349. 36
350. Enrolled Partici pants (NYB C)	351. N YBC Locator Form (Attach ment #3e)	352. 8 0	353. 1	354. 5 /60	355. 7
356. Enrolled Partici pants (NYB C)	357. N YBC Baselin e Assess ment (Attach ment #3h)	358. 8 0	359. 1	360. 4 5/60	361. 60
362. Enrolled Partici pants (NYB C)	363. N YBC Follow- up Assess ment (Attach ment #3h)	364. 8 0	365. 1	366. 4 5/60	367. 60
368. Potential Partici pants (UNC G)	369. U NCG Screene r (Attach ment #3c)	370. 2 00	371. 1	372. 5 /60	373. 17
374.	375. U	376. 8	377. 1	378. 5	379.

Enrolled Participants (UNC G)	NCG Locator Form (Attachment #3f)	0		/60	7
380. Enrolled Participants (UNC G)	381. U NCG Baseline Assessment (Attachment #3i)	382. 8 0	383. 1	384. 2 0/60	385. 27
386. Enrolled Participants (UNC G)	387. U NCG Follow-up Assessment (Attachment #3i)	388. 8 0	389. 1	390. 2 0/60	391. 27
392. Total	393.	394.	395.	396.	397. 335

398.

399.

400. **12B. Estimated Annualized Burden Costs**

401. Annualized cost to respondents for the burden hours is provided in Exhibit A.12.B. Because we do not know a typical job category for these selected participants (or even whether they will be employed at all), costs for participants were estimated using \$7.25 per hour, the average minimum wage across the country as of July 2009. The estimated annual cost to participants for the hour burden for collections of information will be \$2,428.75.

402.

403. Exhibit A.12.2

404. Type of Respondent	405. Total Burden 406. Hours	407. Hourly Wage Rate	408. Total Respondent Cost
409. Potential Participants: Screener (SUNY)	410. 33	411. \$ 7.25	412. \$239.25
413. Potential Participants: Locator Form (SUNY)	414. 7	415. \$ 7.25	416. \$50.75

417. Enrolled Participants: Baseline Assessment (SUNY)	418. 27	419. \$ 7.25	420. \$195.75
421. Enrolled Participants: Follow-up Assessment (SUNY)	422. 27	423. \$ 7.25	424. \$195.75
425. Potential Participants: Screener (NYBC)	426. 36	427. \$ 7.25	428. \$261.00
429. Enrolled Participants: Locator Form (NYBC)	430. 7	431. \$ 7.25	432. \$50.75
433. Enrolled Participants: Baseline Assessment (NYBC)	434. 60	435. \$ 7.25	436. \$435.00
437. Enrolled Participants: Follow-up Assessment (NYBC)	438. 60	439. \$ 7.25	440. \$435.00
441. Potential Participants: Screener (UNCG)	442. 17	443. \$ 7.25	444. \$123.25
445. Enrolled Participants: Locator Form (UNCG)	446. 7	447. \$ 7.25	448. \$50.75
449. Enrolled Participants: Baseline Assessment (UNCG)	450. 27	451. \$ 7.25	452. \$195.75
453. Enrolled Participants: Follow-up Assessment (UNCG)	454. 27	455. \$ 7.25	456. \$195.75
457. Total	458. 387	459.	460. \$2,428.75

461.

462.

463.

464. 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

465.

466. There are no costs to respondents other than their time.

467.

468.

469. 14. Annualized Cost to the Federal Government

470.

471. Assuming an annual salary of \$90,000 for the Project Officer, \$84,000 for the Co-Project Officer, \$100,000 for the Senior Consultant, \$55,000 for the Project Coordinator, \$65,000 for the Data Manager/Statistician, the total cost per year for government personnel is \$153,500, based on the percentage time spent by each on this data collection (see table below for time allotments). It is estimated that operational expenses for this data collection will be \$9,000 for travel. CDC travel is related to providing technical assistance and site visits, as well as attending trainings. This grant (cooperative agreement) has been awarded to three sites: New York Blood Center, State University of New York, Downstate Medical Center, and the University of North Carolina, Greensboro. These are the entities responsible for conducting the study. This grant includes costs for salaries, travel, equipment, supplies and incentives. The grant also covers funds for developing IRB protocols, information collection requests, data management and validation systems and conducting data analysis. The summary for the annualized cost is listed below in Exhibit A.14.1. The annualized cost for the three sites, including direct costs to the federal government is \$828,500.

472. Exhibit A.14.1: Estimates of Annualized Costs to the Federal Government

473.

474. The annual cost is summarized in Exhibit A.14.1

475.

476.

477. Expense Type	478. Expense Explanation	479. Annual Costs (dollars)
481. Direct Costs to the Federal Government	482. CDC Project Officer (GS-13, .45 FTE)	484. \$40,500
485.	486. CDC Co-Project Officer (GS-13, .50 FTE)	488. \$42,000
489.	490. CDC Senior Consultant (GS-14, .05 FTE)	492. \$5,000
493.	494. CDC Project Coordinator (Contractor, .80)	496. \$44,000
497.	498. CDC Data Manager/Statistician (Contractor, .20)	500. \$13,000
501. Operational	502. Travel	503. \$9,000
504.	505. Subtotal, Direct Costs to the Government	506. \$153,500
507. Contractor	508. New York Blood Center	509. \$2

and Other Expenses		25,000
510.	511. State University New York-Downstate	512. \$2 25,000
513.	514. University of North Carolina, Greensboro	515. \$2 25,000
516.	517. Subtotal, Contracted Services	518. \$6 75,000
519.	520. TOTAL COST TO THE GOVERNMENT	521. \$8 28,500

522.

523. Salary estimates were obtained from OPM salary scale at:

524. <http://www.opm.gov/oca/09tables/html/atl.asp>.

525.

526.

527. **15. Explanation for Program Changes or Adjustments**

528.

529. This is a new data collection.

530.

531.

532.

533. **16. Plans for Tabulation and Publication and Project Timeline Schedule**

534.

535. **Exhibit A.16.1: Project Time Schedule**

536.	537. Activity	538.	539. Time Schedule
540.	542. Development of intervention manuals, personnel training, and related administrative tasks	543.	2– 3 months after OMB approval
544.	Begin recruiting participants, baseline assessment, and intervention implementation	545.	3–7 months after OMB approval
546.	Conduct 3 month follow-up	547.	6 – 10 months after OMB approval
548.	Data management and validation	550.	3– 12 months after OMB approval
549.	551. Evaluate findings	552.	12 – 16 months after OMB approval
553.	Disseminate findings	554.	16– 24 months after OMB

555.

556.

557. **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

558. No exception is requested. We will display the OMB Expiration date.

559.

560. **18. Exceptions to Certification for Paperwork Reduction Act (PRA)**

Submissions

561. There are no exceptions to certification for Paperwork Reduction Act guidelines of 5 CFR 1320.5.

562.